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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,708	02/05/2001	Richard D. Cramer	3017-54	5704

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EXAMINER

ZEMAN, MARY K

ART UNIT PAPER NUMBER

1631

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/776,708

### Applicant(s)

CRAMER ET AL.

### Examiner

Mary K Zeman

### Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-10 are pending. Claims 2-10 are newly added. Claim 1 is amended.

Applicant's arguments filed 9/8/03 have been fully considered but they are not completely persuasive. Any rejections not reiterated below have been withdrawn.

### ***Rejections maintained***

Claim 1 remains rejected *and claims 2-10 are newly rejected* under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. To the extent this rejection is newly applied, it is applied to newly added claims.

Applicant argues that the representative conformations of reactant molecules that are generated by the claimed methods represent a concrete tangible and useful result. However, this argument is not persuasive. What the claimed methods do is generate data-based representations which simulate potential conformations of non-existing molecules. This does not meet the standard of a concrete, tangible and useful result. The claims which end with COMFA steric field determinations are similarly non-statutory, as this calculation (the COMFA steric field) is a manipulation of data to an end which is not concrete, tangible and useful. The claims that end with calculating field differences are also not concrete tangible and useful, as it is not set forth in the claim what one is to do with that particular number/ calculation, or what the difference value means. As such, these claims fail to meet the threshold of being concrete, tangible and useful. The case law cited below (and previously) indicates that when a method provides a data value, calculation, or number that is immediately useful, such as a dollar value, or a Yes/No, Buy/Sell answer, such claims meet the threshold. These claims do not recite methods providing such end results.

MPEP 2106: "For such subject matter to be statutory, the claimed process must be limited to a practical application of the abstract idea or mathematical algorithm in the technological arts. See *Alappat*, 33 F.3d at 1543, 31 USPQ2d at 1556-57 (quoting *Diamond v. Diehr*, 450 U.S. at 192, 209 USPQ at 10). See also *Alappat* 33 F.3d at 1569, 31 USPQ2d at 1578-79 (Newman, J., concurring) ("unpatentability of the principle does not defeat patentability of its practical applications") (citing *O'Reilly v. Morse*, 56 U.S. (15 How.) at 114-19). A claim is limited to a practical application when the method, as claimed, produces a concrete, tangible and useful

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result; i.e., the method recites a step or act of producing something that is concrete, tangible and useful. See AT &T, 172 F.3d at 1358, 50 USPQ2d at 1452. Likewise, a machine claim is statutory when the machine, as claimed, produces a concrete, tangible and useful result (as in *State Street*, 149 F.3d at 1373, 47 USPQ2d at 1601) and/or when a specific machine is being claimed (as in *Alappat*, 33 F.3d at 1544, 31 USPQ2d at 1557 (in banc))."

Claim 1 remains rejected and *new claims 2-10 are newly rejected* under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. To the extent this rejection is newly applied, it is applied to newly added claims.

Applicant argues that the idea of a "representative structure" is described in the specification. However, the metes and bounds of the claims reciting this term are still unclear. Applicant further argues about how the claims teach away from the prior art, however, this does not address the issue of indefiniteness. Each of claims 1-10 recite the term "representative structure." The steps of the claims do not indicate *how* a representative structure is generated, and identified. It would appear that the application of the topomeric alignment rules to one or more reactants would result in the generation of a number of differing potential conformations for each molecule. How does one pick what is "representative" out of those structures that are generated? Are all the generated structures considered representative? Or is it a subset of those generated? What are the rules guiding the selection of the subset? As pointed out in the response, one of skill in the art would generally NOT pick the conformations applicant intends, as they are not necessarily similar to those found in "real life", but the claim is silent on how to select ones that are "representative" according to Applicant's standards.

The metes and bounds of claims 2, 5, 6, 9 and 10 are unclear. These claims recite the term "fragment" which is not clearly defined in the specification, and it is not clear how Applicant intends the term to be interpreted. Exactly what the fragments are of, is unclear. The term fragment is referred to in the specification when discussing prior art 2D and 3D fingerprinting, and at one place as a portion of a molecule being 2-7 atoms in length. However, none of these references are made in connection with Applicant's methods or definitions. A

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fragment can be as small as one atom, or as large as an entire protein structure that merely lack a hydrogen. It is unclear how to “apply” a descriptor (a math based rule) to a fragment of anything, unless it is to another piece of data.

In claims 7-10 it is unclear how the steps of the method meet the limitation in the preamble for “applying a molecular structural descriptor. Claim 7 ends with the calculation of field differences between all pairs of reactants. This does not seem to be the same goal. Claim 9 has a similar problem. Also, there is no clear step where any molecular structural descriptor is applied (other than possibly adding the hydrogen bonding fields). Structures are generated by applying topomeric rules (which do *not* appear to be the same as a molecular structural descriptor), fields are determined, and differences are calculated.

Claim 1 remains rejected *and claims 2-10 are newly rejected* under 35 U.S.C. 102(b) as being anticipated by Cramer, III et al. (USP 5,307,287- of record in 08/592132). To the extent this rejection is newly applied, it is applied to newly added claims.

Applicant argues that the COMFA patent does not teach the methods of the pending claims, that it does not teach the application of the method to “fragments” as opposed to entire proteins, and that the patent requires alignment to a particular conformer. Applicant’s arguments have been fully considered, but are drawn to limitations not present in the rejected claims. The claims as written do not require small pieces of a molecule. A “reactant molecule” is not an exclusion of a protein, and the indefiniteness of the term “fragment” has been discussed above. The term “reactant molecule” does not appear to be specifically defined in the specification, and, given its broadest reasonable interpretation, could be anything which reacts. Further, the claim does not exclude alignment against any particular conformer, as there are no specific topomeric alignment rules set forth in the claim. They are left to one of skill in the art to “define” in step (a) of the claimed methods. As set forth in the patent, the methods allow the user to see the areas of molecular shape most important to activity highlighted on the screen. This is generation of representative 3D conformations as required by claims 1-2. This also is a “characterization” of a 3D structure as required by claims 3-6. This is also the application of a structural descriptor as required by claims 7-10.

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### ***New Grounds of Rejection***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-7 of U.S. Patent No. 6,185,506. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims as added and/or amended now recite the same steps to the same ends, even though the wording is slightly different. For example, Claim 1 of the application requires the generation of topomeric alignment rules, and their application to reactants to generate 3D structures. Claim 4 of the patent topomerically aligns the reactants- which is the same as generating the rules and applying them to reactants. Further dependent claims require the determination of COMFA fields, and hydrogen bonding fields in both the application and the patent. As such they are claiming the same methods..

#### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. In January, after the move to the new facilities, the phone number will be: (571) 272-0723.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028. In January, after the move to the new facilities, the phone number will be: (571) 272-0722.

The Official fax number for this Art Unit is: (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz

11/26/03

  
MARY K. ZEMAN  
PRIMARY EXAMINER  
